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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,207	08/28/2003	Aaron W. Janke	279.093US3	9733

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT PAPER NUMBER

3762

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,207

Applicant(s)

JANKE ET AL.

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 9-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Advisory Action (2 sheets)</u> . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/31/06 has been entered.

Election/Restrictions

Claims 9-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the telephone conversation of 3/30/06.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7, 8, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bisping (4886074).

Bisping discloses the claimed invention in figures 1-5 with electrode, 3, guiding mechanism, 8, movement assembly, 5, 9, and 3, with piston, 5, base, 3, knob, 9 or 12, slot, 10 or 11a, and helix, 7, except for the mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Bisping, with a mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant since it was known in the art that heart leads use a mesh screen disposed on the electrode tip to allow fibrous connective tissue to intertwine with the screen to firmly secure the electrode and since it was known in the art for heart leads to use a helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant, to provide a biocompatible coating that does not degrade/breakdown in the body, to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing and pacing, the conforming coating to allow the fixation to still be inserted into the heart with out causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix.

Claims 1, 2, 3, 7, 8, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi (4624265).

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Grassi discloses the claimed invention in figure 4 with electrode, 21, guiding mechanism, 20, movement assembly, 14 and 17, seal, 16, base, 17, and piston, 14 between seals 16, and helix, 15, except for the mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Grassi, with a mesh screen disposed on the electrode tip and the helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant since it was known in the art that heart leads use a mesh screen disposed on the electrode tip to allow fibrous connective tissue to intertwine with the screen to firmly secure the electrode and since it was known in the art for heart leads to use a helix having a non-soluble insulating conforming coating with an active ingredient, such as an anti-inflammatant, to provide a biocompatible coating that does not degrade/breakdown in the body, to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing and pacing, the conforming coating to allow the fixation to still be inserted into the heart with out causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grassi.

Grassi discloses the claimed invention except for the knob and slot mating with the knob to form a stop mechanism. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart lead as taught by Grassi, with a knob and slot mating with the knob to form a stop mechanism since it was known in the art that heart leads

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use a knob and slot mating with the knob to form a stop mechanism to prevent the helix from being retracted further into the lead and causing damage to the lead.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bisping or Grassi as applied to claim 1 above. The modified Bisping or Grassi discloses the claimed invention with a traveling helix through a mesh screen except for the groove guide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the mesh and helical lead as taught by the modified Bisping or Grassi, with a groove guide since it was known in the art that leads with traveling helixes use a groove guide to guide the helix through the distal end of the lead body/mesh to smoothly guide the helix to exit and enter the lead body.

Response to Arguments

Applicant's arguments filed 7/31/06 have been fully considered but they are not persuasive. The argument that Dutcher does not show a non soluble coating on the helix containing a drug is not persuasive. Dutcher shows in figures 5, 8, and 9, the use of a "plastic" drug plug covering part of the helix and therefore is one showing of many teaching the use of a "non soluble insulating material" coated on "at least a portion" of the helix "including an active ingredient". In addition, Altman describes in columns 14 and 15 the use of a polymer drug release device on a helix for therapeutic purposes. In addition, Altman and Bisping or Grassi are both related to the same subject matter, helical fixation devices for heart tissue, with Altman specifically noting the use of the polymer drug release device on the helix for therapeutic purposes. Finally, it is well known (from the previously cited art discussed below) that helixes include non soluble insulating materials on their surface to change the impedance of the helix

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and Hoffman shows the use of applying a drug anywhere on a non soluble insulating material of a fixation lead.

The previous cited art shows several examples of many of the well known in the art features described in the 103 rejections. Some of these references include: Dutcher, '028, helix, mesh, drug non-soluble conforming insulative coating on helix; Pohndorf et al, '178, drug coating on a helix; Struble, '531, non-soluble conforming insulation on a helix; Altman, '427, drug non-soluble conforming insulative coating on helix; Heil, '661, mesh screen, drug, and helix; Hoffmann et al, '329, drug non-soluble conforming insulative coating on fixation device; Ocel, '006, knob and slot; Jammet, '534, knob and slot; Vachon, '780, groove guide; and Bisping, '074, groove guide.

In addition, the argument that the examiner has provided insufficient motivation to modify the cited references for each of the 103 rejections/combinations is not persuasive. The examiner has provided proper motivation for each 103 rejection using well known features of cardiac leads. The motivation for each 103 rejection can be seen in the last sentence of the rejections, such as "to provide a biocompatible coating that does not degrade/breakdown in the body, to allow the electrical properties (impedance, current density, etc) of the helix to be changed for more effective sensing and pacing, the conforming coating to allow the fixation to still be inserted into the heart with out causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix". Also, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching,

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suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, each primary reference (Bisping or Grassi) is a cardiac fixation lead and each secondary reference (e.g. Struble, Hoffman, Dutcher, etc) showing a well known feature is a cardiac fixation lead. The secondary references all providing some motivation for the combination. The combined teachings of the references (or features that are well known in the art) used in the 103 rejections would have suggested the claimed invention to those of ordinary skill in the art.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

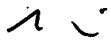
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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


George R Evanisko
Primary Examiner
Art Unit 3762

8/2/06

GRE
August 2, 2006